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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,412	04/15/2004	Sabine Behrends	Serie 6292	9359

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EXAMINER	
MCKANE, ELIZABETH L	
ART UNIT	PAPER NUMBER
1797	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,412	BEHRENDS ET AL.	
	Examiner	Art Unit	
	ELIZABETH L. MCKANE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-25,28-42,44-76,79 and 80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-25,28-42,44-76,79 and 80* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 23-25, 28-33, 35-40, 42, 43, 45-65, 67-70, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. (US 5,539,001) in view of Hachmann et al. (US 5,646,105) and Tu et al. (WO 92/09309).

With respect to claims 23-25, 28-33, 35-37, 59, 63, 65, 69, 70, and 72, Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C_{6-22} alkoxymethyl group. See Abstract and Formula II (col.1, lines 50-57). The composition disclosed by Waldmann-Laue et al. may be an aqueous or anhydrous solution. See col.2, lines 6-10. The aromatic alcohol may be benzyl alcohol (an arylalkanol) or phenylethanol (an arylalkanol). See col.2, lines 11-14. The composition may further include a salt, magnesium sulfate (col.3, line 30) and is effective against bacteria and fungi (col.3, lines 44-48 and Examples). The ether to alcohol weight ratio is 1:9, which converts to 0.11. See Abstract. Furthermore, Waldmann-Laue et al. discloses treatment at ambient temperatures. Waldmann-Laue et al. is silent with respect to the

claimed ratio of glycerol ether to alcohol, the disinfection of thermolabile surfaces, and to the claimed treatment temperature.

Hachmann et al. discloses a disinfectant composition containing a disinfectant in combination with an aromatic alcohol as a solubilizer. The ratio of aromatic alcohol to disinfectant is about 1:0.5 to 1:0.07. See col.1, lines 49-53. It would have been obvious to increase the amount of alcohol in the composition of Waldmann-Laue et al. as Hachmann et al. teaches that this ratio of alcohol is effective in promoting stability of the disinfectant compositions at low temperatures and for extended periods of time. See col.1, lines 54-58.

Tu et al. teaches a method of sterilization of thermolabile hard surfaces using a mixture of a glycidyl ether and an aromatic alcohol. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to increase and optimize the treatment temperature, an established result effective variable, based upon the particular concentration of sterilant used and the amount of contamination present, to both increase the percent kill and to reduce the treatment time.

As to claims 39 and 40, Waldmann-Laue et al. fails to teach a method of application on hard surfaces. Tu et al., however discloses that the hard surface may be submerged in the disinfectant for sterilization (page 7, lines 22-24). As submerging

(dipping) the hard surface promotes contact and wetting of the entire surface with the disinfectant, it would have been obvious in the method of Waldmann-Laue et al..

With respect to claim 42, Waldmann-Laue et al. teaches the disinfection of "hard surfaces" but does not enumerate any specific surfaces. However, one of ordinary skill in the art at the time of the invention would have recognized the term "hard surfaces" to includes at least one of metal, glass, plastic, and ceramic, as known in the art.

With respect to claim 43, Waldmann-Laue et al. is silent with respect to disinfecting a medical instrument. However, Tu et al. teaches that medical instruments can be successfully sterilized using organic ether compositions. Thus, it would have been obvious to one of ordinary skill in the art to use the composition of Waldmann-Laue et al. to sterilize medical instruments in the manner of Tu et al.

As to claims 45-47, Waldmann-Laue et al. fails to teach a treatment time. Tu et al. discloses that "[t]he optimum sterilization time is related to the quantity of microorganism present and the level of sterility assurance desired. Consequently, the time can be varied according to needs." See page 8, lines 1-4. In view of the teachings of Tu et al., it would have been obvious to optimize treatment time according to other result effective variables, such as concentration of disinfectant, treatment temperature and the quantity of microorganisms present.

With respect to claims 48-58, Waldmann-Laue et al. discloses that the antimicrobial diol (glycerol ether) and the alcohol are present in a ratio of 9:1 to 1:9 (claim 1). This means that the glycerol either is present in an amount of 10-90% of the composition before any dilution and the alcohol is present in an amount from 90-10%

before any dilution. It is deemed obvious to one of ordinary skill in the art to optimize the relative amounts of the glycerol ether and the alcohol for the particular use of the composition. Moreover, one would have found it obvious to also optimize the dilution amount for the same reasons. The optimization of concentration, a result effective variable, is readily determined through routine experimentation and is deemed obvious in the absence of unexpected results.

With respect to claim 60, while Waldmann-Laue et al. is silent with respect to the treatment pH, it would have been obvious to maintain the pH near neutral in order to avoid the corrosive effects of a strong basic or acidic solution.

As to claims 61-62, Waldmann-Laue et al. teaches generally C_{6-22} alkyls which include both straight and branched chains. Moreover, a chain length of 6 to 22 carbon atoms in the alkoxymethyl group encompasses the claimed ethers and thus, they are rendered obvious by the disclosure of Waldmann-Laue et al..

With respect to claims 64, 67, and 68, although Waldmann-Laue et al. teaches the use of an aromatic alcohol as an essential part of the composition, an arlyoxyalkanol is not disclosed. However, Hachmann et al. evidences the functional equivalence of phenoxypropanol and phenoxyethanol with benzyl alcohol. See Table; col.3, lines 45-60. Thus, it would have been obvious to substitute one for the other in the invention of Waldmann-Laue et al..

3. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al. in view of Hachmann et al. and Tu et al. as applied to claim 23 above, and further in view of Langford (US 5,906,802).

The combination of Waldmann-Laue et al. with Tu et al. discloses the use of elevated temperatures but does not teach using an elevated pressure. Langford discloses that using alternating cycles of pressure and suction, assists with the cleaning action and assures that any sterilant is forced throughout the medical instrument. See col.8, lines 55-59. Since the combination of Waldmann-Laue et al. with Tu et al. teaches the sterilization of medical instruments, it would have been obvious to apply the method of cyclic pressurization of Langford to method of the combination.

4. Claims 41 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claims 23 and 69 above, and further in view of Saud et al. (US 2004/0001797).

With respect to claim 41, Waldmann-Laue et al. does not teach atomizing the composition. Saud et al. discloses a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may be dispensed from a spray bottle (i.e. atomized). See paragraph [0054]. As atomization is an efficient means of providing even coverage of a surface, it would have been an obvious means of dispensing the composition of Waldmann-Laue et al..

As to claim 71, Waldmann-Laue et al. is silent with respect to triclosan within the composition. Saud et al. teaches a disinfecting composition containing a glycerol ether in combination with an alcohol. The composition may additionally include Triclosan to further improve the disinfecting action (paragraph [0037]). For this reason, it would have been obvious to include Triclosan in the composition of Waldmann-Laue et al..

5. Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claim 43 above, and further in view of Miner et al. (US 6,096,348).

The combination of Waldmann-Laue et al. with Tu et al. teaches the treatment of thermolabile hard surfaces but not the treatment of an endoscope. Miner et al. discloses it was known in the art at the time of the invention that medical instruments such as endoscopes are particularly hard to sterilize due to their sensitivity to high temperatures and pressures. As the sterilant of Waldmann-Laue et al. is effective at low temperatures, it would have been obvious to use for the sterilization of endoscopes.

6. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Waldmann-Laue et al., Hachmann et al., and Tu et al. as applied to claim 63 above, and further in view of Eggensperger et al. (US 5,393,789).

Although Waldmann-Laue et al. teaches the use of an aromatic alcohol as an essential part of the composition, an oligoalkanol aryl ether is not disclosed. Eggensperger et al. teaches a surface disinfectant including an antimicrobial in combination with an aromatic alcohol. Suitable aromatic alcohols include the arylalkanols (phenyl ethanol, phenyl propanol, benzyl alcohol) of Waldmann-Laue et al. as well as oligoalkanol aryl ethers. See col.2, lines 41-68. As the disclosure of Eggensperger et al. teaches the functional equivalence of these three types of aromatic alcohols, one of ordinary skill in the art would have found it obvious to substitute one for

another in the composition of Waldmann-Laue et al. and to have an expectation of success when doing so.

7. Claims 73 and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford (US 5,906,802) in view of Waldmann-Laue et al. and Tu et al..

Langford teaches a method of sterilizing a medical instrument (endoscope) wherein the instrument is first cleaned with a detergent to remove bioburden therefrom, disinfected with a liquid or gas sterilant, rinsed with sterile water, and then dried. See col.1, lines 40-52; col.2, lines 35-42; col.3, lines 16-19; col.5, lines 25-26. Although Langford is silent with respect to a disinfection time, it is deemed obvious to optimize the time the sterilant is in contact with the instrument dependent upon the concentration of sterilant, the temperature of the sterilant, and the amount of contamination present. It is noted that all of contact time, temperature, and concentration are result effective variables. Normally, the change or optimization of a result effective variable would be considered an unpatentable modification in the absence of unexpected results. Langford does not disclose use of an alkyl glycerol ether as the sterilant or a treatment temperature.

Waldmann-Laue et al. teaches a method for the disinfection of hard surfaces using a composition containing an aromatic alcohol and a glycerol ether having a C_{6-22} alkoxymethyl group. Since the sterilant of Waldmann-Laue et al. is effective at low-temperatures, it would have been an obvious choice for the sterilization of the thermolabile medical instruments of Langford. With respect to "pre-cleaning" (i.e. rinsing) the instrument with water before the initial step of cleaning, Langford discloses

that the method employs several cycles of washing, either with or without a detergent, in order to completely remove the bioburden prior to sterilization. See col.1, lines 47-51.

Tu et al. teaches a method of sterilization of thermolabile hard surfaces using a mixture of a glycidyl ether and an aromatic alcohol. Tu et al. further discloses that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to increase and optimize the treatment temperature, an established result effective variables, based upon the particular concentration of sterilant used and the amount of contamination present, to both increase the percent kill and to reduce the treatment time.

8. Claims 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langford and Waldmann-Laue et al. as applied to claim 73 above, and further in view of Tu et al..

Langford fails to disclose a treatment temperature. Tu et al. teaches in a method of sterilization that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally maintained from room temperature to about 100 °C. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 31-33, 37, and 51-53 of copending Application No. 10/445,715 in view of Tu et al.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the co-pending claims substantially encompasses the subject matter of the instant claims. The co-pending claims do not claim a treatment temperature. Tu et al., however, teaches in a method of sterilization that the "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time." For the treatment of hard surfaces, the temperature is generally

maintained from room temperature to about 100 ºC. See page 7, lines 22-34. Thus, it would have been obvious to optimize the treatment temperature according to the type of instrument being sterilized to both increase the percent kill and to reduce the treatment time.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 73-81 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 67-73, 75, and 80 of copending Application No. 10/825,266. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of the copending application and the instant claims differ only in that the instant claims recite "thermal" disinfection. However, as no particular temperature is claimed, the copending claims read on the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

12. Applicant's arguments filed 13 June 2008 have been fully considered but they are not persuasive.

13. Applicant argues on page 12 of the Response that Hachmann would actually suggest a lower amount of alcohol. However, applicant only uses the total amount of alcohol used in Hachmann to support this argument. As the claims are directed to the

ratio of glycerol ether to alcohol, as opposed to the total amount of alcohol, this argument seems to be irrelevant. What Hachmann does teach is the claimed ratio and a motivation to employ this particular ratio in the invention of Waldmann-Laue et al..

14. On page 13 of the Response, Applicant submits that Tu et al. fails to teach the claimed weight ratio or that the composition of Waldmann-Laue et al. could be used for the disinfection of thermolabile materials. In response, the Examiner notes that Tu et al. is not required to teach the weight ratio as Hachmann has been relied upon for this teaching. As to the disinfection of thermolabile materials, Tu et al. teaches a similar composition used in this manner and one of ordinary skill in the art would have expected the composition of Waldmann-Laue et al. to be successful when used in the manner of Tu et al..

15. Applicant argues on page 18 of the Response that neither Langford nor Waldmann-Laue et al. disclose thermochemical treatment for 1-20 minutes. Moreover, in the absence of unexpected results, it is submitted that the optimization of treatment time, a known result effective variable, is within the purview of one of ordinary skill in the art. Tu et al. supports this position, teaching that "percent kill can usually be increased just by increasing the temperature of the solution and/or extending the sterilization time."

16. Furthermore, as to applicant arguments on page 18 of the Response that Waldman-Laue et al requires greater than 3 days to achieve sterilization, the examiner remains unconvinced that the difference in treatment time between Waldmann-Laue et

al. and the instant invention is anything more than a difference initial treatment parameters since the composition of Waldmann-Laue et al. is so similar to that claimed.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
14 October 2008